Remarks

This paper responds to the final Office action in the above-entitled application, mailed April 2, 2008, and allowing three months for a response. This response is timely because an extension of the time for response (two months) is being filed with this paper.

This paper is the submission accompanying a request for continued examination. Claims 1 and 2 have been amended in this paper.

The applicant respectfully submits that claims 1-35 are patentable for the reasons provided below.

35 U.S.C. § 103 (Non-obviousness)

The applicant has been asked to show that claims 1-3, 10, 21-25, and 30-34 in this case are non-obvious over the Alford et al. references, in view of McKelvey et al. and Bacchi et al.; claims 3-9 and 35 are non-obvious over the Alford et al. references, in view of McKelvey et al. and Bacchi et al., further in view of Olympus; and claims 11-20 and 26-29 are non-obvious over the Alford et al. references, in view of McKelvey et al. and Bacchi et al., further in view of Owen et al. The applicant respectfully submits that these claims are non-obvious, for the reasons provided below.

The cited prior art references all fail to show "portable apparatus for maintaining an *ex vivo* organ in a viable condition for transplantation," in which "the organ container, the bubble remover, the oxygenator, and the perfusion loop are permanently joined together in fluid-conducting relation to define a single, sterile, closed unit," as claim 1 recites and the remaining claims incorporate by reference back to claim 1.

Alford et al. does not disclose that "the organ container, the bubble remover, the oxygenator, and the perfusion loop are permanently joined together in fluid-conducting relation to define a single, sterile, closed unit," as the present claims require. Alford et al. discloses the use of quick connect/disconnect fittings, for example at the connections at the pump 4 in Figure 4, which is broken at or near 5, opening the perfusion loop, to

remove the perfusion loop. Alford, et al. therefore does not achieve a benefit of each claim, which is that the perfusion loop assembly can be provided in a single sterile package, loaded with an organ and perfusion fluid and closed in a sterile field, then moved into operative contact with the pump, optionally out of the sterile field, while the perfusion fluid loop remains closed, so the pump and other associated apparatus does not need to be sterilized and can be re-used.

Similarly, McKelvey et al. does not disclose that "the organ container, the bubble remover, the oxygenator, and the perfusion loop are permanently joined together in fluid-conducting relation to define a single, sterile, closed unit," as the present claims require. As stated in McKelvey et al., col. 5, lines 29-38,

> The perfusion sector or "perfusion circuit" includes the housing 10 which receives the organ, the venous reservoir 11, the blood pump 12, the heat exchanger 13, the oxygenator 14, the blood filter 15, the blood flow meter 16, the sensor probes 17, the pressure monitor 18, the temperature probe 25, the sampling conduit 23, the blood exchange pump 27, and reservoirs 28 and 29 (for holding blood passing into and out of, respectively, the perfusion circuit).

But McKelvey et al. goes on, in col. 5, lines 38-42, to say that some of the above elements of the perfusion circuit are removable from the remainder of the circuit, and thus not permanently joined:

> As shown in Fig. 3, the organ housing or reservoir 10, the venous reservoir 11 (not visible), the blood pump 12, the heat exchanger 13, and the oxygenator 14 are included within a "transpack" removable organ unit 31.

(emphasis added.) McKelvey et al. confirms that the portions of the perfusion circuit defined as the organ unit 31 are removable from the rest of the perfusion circuit and taken separately to the sterile field to receive an organ. McKelvey et al., col. 6, lines 1-13.

Bacchi et al. similarly does not disclose that "the organ container, the bubble remover, the oxygenator, and the perfusion loop are permanently joined together in fluid-conducting relation to define a single, sterile, closed unit," as the present claims require. Bacchi et al. states at col. 6, lines 33-53 (emphasis added here), with reference to Fig. 2 showing the transporting vessel 63 for receiving the organ O:

> The transporting vessel 63 essentially comprises a body 630 with a nozzle 631 intended for being connected to the portion of the pipework 66 which serves as pipe 62 for connecting the nozzle 631 of the vessel 63 to the nozzle 620 of the collector bag 62. The body 630 is intended for receiving a lid 632 optionally held in place by a fastening of any appropriate type, for example having a screwed joint, elastic fixture, "frog" . . . As is seen in the drawing, this lid 632 has various openings. Among these various openings figures an approximately semi-circular peripheral notch 634 which is intended for the passage of the pipe 661 going to the dispensing element 65. Among these openings also figures an approximately rectangular slot 635 which emerges at the periphery of the lid and which is intended for receiving, preferably by sliding, the suspension device 64. In addition to this notch and this slot, these openings also comprise perforations 636 which are distributed in a circle close to the periphery of the lid, and to which reference will be made further. All this is clearly shown in the figures of the drawing.

In Bacchi et al., the body 630 and lid 632 which contain the organ are open, so the organ does not reside in a "closed" system as the present claims require.

Olympus, based on review of the drawings (as the text is in Japanese), does not disclose that "the organ container, the bubble remover, the oxygenator, and the perfusion loop are permanently joined together in fluid-conducting relation to define a single, sterile, closed unit," as the present claims require. The drawing is schematic and does not show how, when, or by what type of connections the parts of an apparent loop are joined.

Owen et al. does not disclose that "the organ container, the bubble remover, the oxygenator, and the perfusion loop are permanently joined together in fluid-conducting relation to define a single, sterile, closed unit," as the present claims require. The tubing 50c of Owen et al. conducts perfusion fluid to the organ (see Figs. 1 and 2). Fig. 1 of Owen et al. shows the upper end of the tubing 50c passing through a small hole in the cabinet, and the tubing is connected to larger structure at each end. The tubing 50c physically cannot be removed from the cabinet without breaking a connection in the path of perfusion fluid.

Thus, none of the references cited for obviousness disclose that "the organ container, the bubble remover, the oxygenator, and the perfusion loop are permanently joined together in fluid-conducting relation to define a single, sterile, closed unit," all of the present claims require this feature, and no reason has been provided why it would be obvious to modify all of the prior art to arrive at the present claimed invention. For these reasons the claimed inventions are not obvious and the rejections should be withdrawn.

Obviousness Type Double Patenting

The judicially created rule against obviousness-type double patenting has been cited respecting numerous claims of this application and various claims of U.S. Patent No. 6,677,150 ("the Alford, et al. US patent"), in view of McKelvey et al. and Bacchi et al., and for some claims further in view of Olympus or Owen et al. This rejection is respectfully traversed because the rule against obviousness-type double patenting only requires that a

claim which is obvious in light of subject matter claimed in a prior issued, commonly-owned patent must expire on the same date as the prior patent.

> [T]he first question [in a double patenting analysis] is: Is the same invention being claimed twice[?] If the answer to that is no, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting. * * * If the rejected claim defines more than an obvious variation, it is patentably distinct."[1]

All of the present claims are patentably distinct, compared to the cited claims of the Alford, et al. US patent. This is so at least for essentially the same reasons provided above in response to the rejections under 35 USC 102 and 103. Therefore, there is no double patenting in this instance, either.

35 U.S.C. § 102(f) or (g) - Alford, et al.

The applicant has been requested to show why the present claims do not raise a priority (102(g)) or derivation (102(f)) issue between the present application and the Alford, et al. US patent. Neither issue arises in this instance, so the issues should be withdrawn.

There should be no priority issue because, as explained above, the present claims and those of the Alford, et al. US patent do not claim obvious variations of the same invention.

---

[1] General Foods Corporation v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 23 U.S.P.Q.2d 1839 (Fed. Cir. 1992) (emphasis in original).

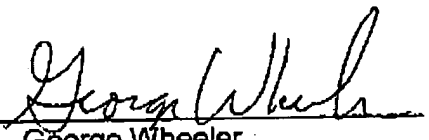
There should be no derivation issue because the present claims are not obvious in view of the disclosure of the Alford, et al. US patent.

Conclusion

The applicant has shown that this application satisfies all the legal requirements pointed out by the Examiner. Therefore, the Examiner is respectfully requested to prepare a Notice of Allowability allowing all the pending claims (1-35).

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: 

George Wheeler
Reg. No. 28,766
Attorney for Applicant(s)

Dated: September 2, 2008

McANDREWS, HELD & MALLOY, LTD.
500 West Madison Street
Chicago, Illinois 60661
Telephone: (312) 775-8000